



ENZYMATIC THERAPY

What **Better** feels like.™

January 3, 2006

Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Maxi-Calm™ with GABA	Improve your mood*	GABA (gamma-aminobutyric acid)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: _____

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: _____

1-3-06

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux
Chief Operations Officer

INTEGRATIVE THERAPEUTICS INC.™

NF Formulas - PhytoPharmica
Tyler Encapsulations - Vitaline Formulas

9755 SW Commerce Circle, Suite B2
Wilsonville, OR 97070
P: 503.582.8386 • F: 503.582.0467

ENZYMATIC THERAPY® & PHYTOPHARMICA®

825 Challenger Drive, Green Bay, WI 54311-8328
P: 920.469.1313 F: 888.570.6460 (Enzymatic)
P: 920.469.9099 F: 920.469.4418 (Phyto)

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Maxi-Calm™ with GABA	Get more sleep*	GABA (gamma-aminobutyric acid)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Maxi-Calm™ with GABA	The brain's natural calming agent to promote relaxation and a restful sleep.*	GABA (gamma-aminobutyric acid)

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Maxi-Calm™ with GABA	GABA is an important amino acid neurotransmitter in the brain. It regulates brain nerve cell functions and has been referred to as the brain's natural calming agent.*	GABA (gamma-aminobutyric acid)

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Maxi-Calm with GABA 4e

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Maxi-Calm™ with GABA	GABA supplementation supports healthy neurochemical balance, a positive mood, and restful sleep.*	GABA (gamma-aminobutyric acid)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

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